

**UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY**

**IN RE: JOHNSON & JOHNSON
TALCUM POWDER PRODUCTS
MARKETING, SALES
PRACTICES, AND PRODUCTS
LIABILITY LITIGATION**

MDL No. 16-2738 (MAS) (RLS)

***THIS DOCUMENT RELATES TO
ALL CASES***

**PLAINTIFFS' STEERING COMMITTEE'S RESPONSE IN
OPPOSITION TO DEFENDANTS' MOTION TO STRIKE
REBUTTAL EXPERT REPORT OF DR. ELIZABETH STUART**

I. INTRODUCTION

The Court should deny Defendants' Motion to Strike Rebuttal Expert Report of Dr. Elizabeth Stuart ("Motion"). Defendants leave out important context about the sequence of the O'Brien 2024 study, Defendants' disclosure of their expert Dr. John Kornak, Dr. Kornak's belated deposition testimony, and the Plaintiffs' Steering Committee's (PSC) disclosure of Dr. Stuart. Plaintiffs' disclosure of Dr. Stuart's opinions was not improper; it was an appropriate response to these events.

Dr. Stuart, the Chair of Biostatistics at Johns Hopkins School of Public Health, is a rebuttal witness who focuses solely on Defendants' expert, Dr. Kornak, a biostatistician who was wholly unknown to talc litigation until he was disclosed on May 28, 2024, and whose testimony and opinions the PSC has moved to strike in their entirety. Defendants argue the PSC disclosed Dr. Stuart as a rebuttal witness

too late. There were good reasons, however, Dr. Stuart's opinions could not have been disclosed any earlier—among them, she responds to certain tardily-disclosed opinions of Dr. Kornak.

Dr. Stuart's report was filed to assist the Court in determining whether to exclude the opinions and testimony of Dr. Kornak. If the Court grants the Motion to Exclude Dr. Kornak, then the Motion at bar is moot. For that reason, the PSC suggests that the Court deny Defendants' Motion without prejudice. To the extent that a deposition of Dr. Stuart is necessary, Plaintiffs are willing to meet and confer on dates. Despite the complaints in Defendants' Motion, they have not actually asked Plaintiffs to depose Dr. Stuart.

II. PROCEDURAL HISTORY

Plaintiffs' view of the procedural history of this dispute is different from Defendants'. Briefly stated, Plaintiffs submit:

The Order of the Court required simultaneous disclosure of all expert reports on May 28, 2024. (ECF No. 32214). In the weeks leading up to the deadline, both sides of this litigation were in full swing working with their experts.

On May 15, 2024, during that intensive period, the O'Brien 2024 paper was published. It appears that neither side in this litigation was aware of the study or expecting the study to be published on that date. Both sides rapidly moved to have their experts address this newly published, peer-reviewed literature, because it is an

extensive, well-designed study of a long-running population cohort that specifically addressed and answered relevant questions and concerns regarding the genital usage of talcum powder and epithelial ovarian cancer. At the time the O'Brien paper was published on May 15, 2024, all Plaintiffs' general and case-specific causation experts had been disclosed (in November 2023), and the last of Plaintiffs' expert depositions were being completed, with the last witness being deposed on May 15, 2024, the date the study was published.

Defendants' expert reports had not been disclosed but were due on May 21, 2024, 6 days after O'Brien 2024 was published. Given the proximity of the defense expert disclosure date, the Court issued a text order extending the time for J&J to disclose its experts by one week, until May 28, 2024. (See MDL Text Order, ECF 32214, May 20, 2024). The Order also gave Plaintiffs the ability to amend their previously disclosed expert reports.

J&J sought to add an entirely new expert, Dr. Kornak, in the discipline of Biostatistics to attack the fundamental methodology of O'Brien 2024. Defendants' expert, Dr. Kornak, had his first contact with Defendants' lawyers on May 20, 2024, before beginning work on his report. (Ex. B, Kornak Dep. 16:2–11.) Defendants disclosed Dr. Kornak, a new expert on a new topic, on the simultaneous disclosure deadline—May 28, 2024. (Ex. A, Kornak Rep.)

As directed, on May 28, 2024, Plaintiffs amended the reports of previously disclosed experts to address O'Brien 2024. While each is an expert in their field, none were professors of Biostatistics as is Dr. Kornak. These experts disclosed their opinions regarding the study, including the significant and strong finding of a 1.81 hazard ratio, as well as how the study fits with other established scientific literature linking asbestos-laden talc exposure with ovarian cancer. Defendants have had the benefit of Plaintiffs' experts' opinions on the O'Brien 2024 study for almost three months now.

By contrast, Dr. Kornak's May 28, 2024 report disclosed some—but not all—of his opinions regarding the O'Brien 2024 study. In general terms, he offered criticism of various aspects of the authors' methodology. For example, Dr. Kornak critiqued the O'Brien 2024 study's use of the multiple imputation methodology to derive known missing data. (Ex. A, Kornak Rep. 3–4, 13–31.) He also raised criticism about the O'Brien 2024 study's hazard ratios and the calculations that led to them. *Id.* at 4, 31–35. While Plaintiffs disagree with these criticisms, they were at least disclosed and open to discovery.

Dr. Kornak was originally scheduled to be deposed on June 27, 2024, but his deposition was rescheduled at his request. Dr. Kornak finally gave his deposition 9 days later on July 8, 2024. That is forty-one (41) days after his expert report was served.

Not only was his deposition highly technical, addressing discrete issues of biostatistics including multiple imputation strategies for dealing with missing data and recall bias corrections, but he disclosed new opinions. At the deposition, *and for the first time*, Dr. Kornak expanded his opinions. In particular, he expressed opinions that the entire O'Brien 2024 study should never have been published, due to flaws in the peer-review process. He testified:

Q. [O'Brien 2024] went through peer review, true?

A. I mean, it did. **I'm amazed it did. I can't understand how—they must have not had biostatistical review, because that was amazing that that got through without—**

(Ex. B, Kornak Dep. 106:21–107:3.)

Q. . . . Is there any possibility in your mind that the peer reviewers could have missed the methodology point of this study, particularly since it's in the title of the article?

A. **Oh, absolutely, I think they did miss it, yeah.**

Q. **Okay. All right. Now, the article, so you think that the peer reviewers and the journal completely missed it?**

A. **Yes, I do. Yeah, I mean, it's—they missed it. I don't know what—I'm surprised that a journal would let that go. I blame it probably on the associate editors for not picking the right range of reviewers, but nobody picked up on the biostatistical problems in this paper.**

Id. at 164:22–165:15.

He went on to state that, “I’m disagreeing with all of them”—all of the peer reviewers, because they “absolutely missed” the failings that he purported to identify in his own report. *Id.* at 174:7–14, 166:18–167:2.

Nowhere *in Dr. Kornak’s report* are his opinions about the peer review process disclosed. In fact, Dr. Kornak trumpets the fact that his *own* opinions were peer reviewed, suggesting that that is relevant. (Ex. A, Kornak Rep. 2, Ex. C, Kornak CV 43.)

And, nowhere *in Dr. Kornak’s report* does he opine that the O’Brien 2024 study is so flawed that it should never have been published.

Faced with a new expert in a new subject area on a new study, coupled with this belated July 8, 2024 disclosure of additional opinions, Plaintiffs were pressed into engaging Dr. Stuart, an expert who has published on the very areas that Dr. Kornak claimed to be an expert in—multiple imputation and missing data corrections. (See Rebuttal Report of Elizabeth Stuart, Exhibit D). Not only are her opinions the subject of the PSC’s Motion to Exclude Dr. Kornak, to opine on Dr. Kornak’s report and his testimony, they are critical to understanding this new, complex, and important study, a study that will continue to be the target of Defendants’ methodological challenges.

To be clear, Dr. Stuart was engaged to act as a rebuttal witness to respond to Dr. Kornak's opinions, which included his methodologic attacks on the O'Brien 2024 study.

Further, while Defendants attempt to frame Dr. Stuart as a witness whose opinions should have been disclosed with the other experts, that mischaracterizes her scope. Plaintiffs disclosed Dr. Stuart as a rebuttal witness in response to Dr. Kornak, a previously undisclosed witness in a specialty which had not been at issue in this case, and his methodological attacks on a peer-reviewed published opinion, O'Brien 2024, which Plaintiffs, candidly, did not expect.

As mentioned above, one of Dr. Kornak's main criticisms is that the O'Brien 2024 authors misused multiple imputation—but he does not actually have experience employing multiple imputation in an epidemiologic study. Dr. Stuart, on the other hand, has made this research methodology an area of focus and expertise. She has a Ph.D. in statistics from Harvard; she studied under one of the originators of multiple imputation theory; and she has published numerous papers and given several presentations on the topic. *Id.* at 1–3. In contrast to Dr. Kornak's, Dr. Stuart's qualifications and expertise on multiple imputation and its methodology are first-rate, and she explains the process in detail.

Dr. Stuart specifically responds to Dr. Kornak's belatedly disclosed opinion, that the peer review process was so poor that the O'Brien 2024 study should not

have been published, on page 13 of her report. Elsewhere in her report, she responds to other parts of Dr. Kornak's deposition testimony and the newly disclosed interpretation of his own expert report during his deposition.

Dr. Stuart's rebuttal report was prepared under almost as tight of a timeline as Dr. Kornak's, and all of Plaintiffs' other experts who discussed the O'Brien 2024 study. Dr. Stuart's report was signed on July 21, 2024, only 13 days after July 8, 2024, and filed on July 23, 2024.

Defendants have never requested a deposition of Dr. Stuart. They have had her report for 30 days as of the date of this filing.

III. LEGAL AUTHORITY

Federal Rule of Civil Procedure 26(a)(2) requires a proposed expert witness to tender a report that discloses "a complete statement of all opinions the witness will express," along with other requirements. "The purpose of Rule 26(a)(2)(B) is to eliminate unfair surprise to the other party, and that goal is not achieved when experts fail to provide key information in or along with their reports." *Amato Subaru of America, Inc. Aquino v. Subaru of America, Inc.*, 2023 WL 7085095, at *3 (D.N.J. Sept. 27, 2023) (quoting *McGuire v. Cirrus Design*, No. 07-683, 2009 WL 383541, at *1 (E.D. Tex. Feb. 13, 2009)).

"Rule 26(a)(2) also authorizes admission of rebuttal expert testimony." *Duncan Grp., LLC v. Cimarex Energy Co.*, 2023 WL 3269699, at *4 (W.D. Okla.

Apr. 18, 2023). The rule contemplates that rebuttal reports be disclosed within 30 days or as a court otherwise may direct. Fed. R. Civ. P. 26(a)(2)(D)(ii). Nothing in Rule 26(a)(2) states that rebuttal experts are disfavored or that their opinions are necessarily circumscribed. On the contrary, “[p]recluding testimony is [the] drastic and disfavored measure,” and doing so—“even when there has not been strict compliance with Rule 26”—may “tend to frustrate the Federal Rules’ overarching objective of doing substantial justice.” *Wechsler v. Hunt Health Systems, Ltd.*, 381 F. Supp. 2d 135, 155 (S.D.N.Y. 2003). *See also Simo Holdings Inc. v. Hong Kong uCloudlink Network Tech. Ltd.*, 354 F. Supp. 3d 508, 510 (S.D.N.Y. 2019) (citing *Wechsler* and extending time to disclose rebuttal experts).

Disclosure of relevant rebuttal expert opinions is squarely within the textual scope of Rule 26(a)(2), as well as the spirit of the Federal Rules as a whole. Defendants are wrong to argue that disclosure of a relevant expert opinion is “highly prejudicial.” (ECF No. 33038-2, Memo. in Support of Motion at 6.) It is axiomatic that evidence is not prejudicial just because it is adverse to one party’s interests.

IV. ARGUMENT

The Court should deny Defendants’ Motion and should not strike Dr. Stuart’s report or her testimony. The three grounds advanced by J&J are all meritless, and there are appropriate remedies for the few legitimate concerns contained within Defendants’ Motion.

First: By disclosing Dr. Stuart as a rebuttal witness, Plaintiffs did not “flagrantly disregard” court orders or attempt gamesmanship with respect to the study. That overinflated rhetoric falls flat next to the practical realities of litigation and evolving science.

The fact is, *both* sides faced a tough job in dealing with a landmark epidemiology study, published on May 15, 2024, just thirteen days before expert reports were required to be disclosed on May 28. Nevertheless, Plaintiffs disclosed multiple experts discussing the study—as did Defendants. Defendants cannot say (and *do* not say) that Dr. Stuart’s report is some curveball or a completely new theory that does not comport with Plaintiffs’ other experts’ opinions. Indeed, it was Plaintiffs who were surprised by the identification of an entirely new expert in an entirely new discipline. In the end, Defendants do not complain at all about the *substance* of Dr. Stuart’s report; only the date on its postmark.

But Defendants fail to tell the Court that it is in fact Dr. Kornak who committed the more serious disclosure violation, by failing to disclose certain additional opinions in his May 28, 2024 written report, and leaving them only to be uncovered during his already postponed (at his request) July 8, 2024 deposition. Chief among these is his assertion that the O’Brien 2024 study is so flawed, that it should never have been published. Defendants and their expert do not have clean hands.

Further, while J&J attempts to frame Dr. Stuart as a witness whose opinions should have been disclosed with the other experts, that mischaracterizes her scope. Plaintiffs disclosed Dr. Stuart as a rebuttal witness in response to Dr. Kornak's methodology attacks on the O'Brien 2024 study.

Second: There is no "I get the last word" clause in Rule 26. (Memo. in Support of Motion at 6) ("[P]laintiffs' untimely disclosure is also highly prejudicial because it has effectively given them the last word on scientific evidence. . . .") What Rule 26 really requires is *fair* disclosure and a *fair* opportunity to discover the opposing party's rationales. While Plaintiffs would give Defendants the opportunity to depose Dr. Stuart, it should be noted that Defendants frustrated that procedural principle when Dr. Kornak showed up to his deposition with new opinions.

The fact remains, that Dr. Stuart's expert report is a pure rebuttal report that responds to Dr. Kornak's report and deposition. Her report was expressly tendered as an exhibit to Plaintiffs' Motion to Exclude Dr. Kornak. (ECF No. 33011-11.) If the Court hears from Dr. Kornak at trial, the Court should also hear from Dr. Stuart who, after all, is an expert in the area of multiple imputation and missing data correction.

Third: Defendants falsely argue or exaggerate that all this "prejudice" is simply irremediable now and for all time. Defendants hang this on the Court's Order, ECF No. 32991 at 2, n.1, that there will not be extensions to "the current briefing

dates.” But this is a unique situation, where the parties are responding to an important new study that was published long after Plaintiffs had already disclosed their experts’ reports and days before Defendants were required to disclose theirs. The parties have met all relevant briefing dates, and no one seeks an extension to those. That part of the Court’s Order does not deal with any necessary supplemental expert discovery or disclosure.

At bottom, what Defendants *really* complain of is that they were not able to take the deposition of Dr. Stuart. However, they have not even asked for it. Denying the motion and allowing Dr. Stuart’s testimony will not affect the Court’s schedule. Daubert briefing will be completed in keeping with the Court’s Scheduling Order, and preparation for the bellwether trial can proceed without any delay.

V. CONCLUSION

Plaintiffs regret that they were not able to disclose Dr. Stuart’s July 21, 2024 report any earlier. But that was in part because of Dr. Kornak’s own late disclosure of new opinions at his July 8, 2024 deposition. And, no one disputes that *all* parties and experts were crunched for time by the publication of the O’Brien 2024 study on May 15, 2024, followed by the expert disclosure deadline on May 28, 2024.

Respectfully, Plaintiffs submit that the most efficient course for the Court at this time is to deny Defendants' Motion without prejudice, and to proceed in considering Plaintiffs' Motion to Exclude Dr. Kornak's opinions.

Given the importance of the O'Brien 2024 study, and the extraordinarily compressed timeframe at issue, the Court should *not* strike Dr. Stuart. Suppressing relevant evidence from the jury would "tend to frustrate the Federal Rules' overarching objective of doing substantial justice." *Wechsler*, 381 F. Supp. 2d at 155. The Court could grant a limited window during which Dr. Stuart could be deposed, and during which time Defendants could file a motion to exclude her, if they still find that necessary.

Dated: August 20, 2024

Respectfully submitted,

/s/ P. Leigh O'Dell

P. Leigh O'Dell

BEASLEY, ALLEN, CROW, METHVIN

PORTIS & MILES, P.C.

218 Commerce St.

Montgomery, AL 36104

Tel: 334-269-2343

leigh.odell@beasleyallen.com

Plaintiffs' Co-Lead Counsel

/s/ Michelle A. Parfitt

Michelle A. Parfitt

ASHCRAFT & GEREL, LLP

1825 K Street, NW, Suite 700

Washington, DC 20006

Tel: 202-335-2600

mparfitt@ashcraftlaw.com

Plaintiffs' Co-Lead Counsel

/s/ Christopher M. Placitella

Christopher M. Placitella

COHEN, PLACITELLA & ROTH, P.C.

127 Maple Ave.

Red Bank, NJ 07701

Tel: 732-747-9003

clpacitella@cprlaw.com

Plaintiffs' Liaison Counsel

CERTIFICATE OF SERVICE

I hereby certify that on August 20, 2024, I electronically filed the foregoing document with the Clerk of the Court using the CM/ECF system which will send notification of such filing to the CM/ECF participants registered to receive services in this MDL.

Respectfully submitted,

/s/ P. Leigh O'Dell

P. Leigh O'Dell